SECTION 3. This Act applies beginning with the 2017-2018 school year.

SECTION 4. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2017.

Passed by the House on May 9, 2017: Yeas 135, Nays 10, 2 present, not voting; the House concurred in Senate amendments to H.B. No. 674 on May 24, 2017: Yeas 104, Nays 40, 3 present, not voting; passed by the Senate, with amendments, on May 23, 2017: Yeas 22, Nays 9.

Approved June 12, 2017.

Effective June 12, 2017.

# PROVISION OF CERTAIN INVESTIGATIONAL STEM CELL TREATMENTS TO PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES AND REGULATING THE POSSESSION, USE, AND TRANSFER OF ADULT STEM CELLS; CREATING A CRIMINAL OFFENSE

#### **CHAPTER 697**

H.B. No. 810

#### AN ACT

relating to the provision of certain investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses and regulating the possession, use, and transfer of adult stem cells; creating a criminal offense.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. This Act shall be known as Charlie's Law.

SECTION 2. Chapter 1003, Health and Safety Code, is amended by designating Sections 1003.001, 1003.002, and 1003.003 as Subchapter A and adding a subchapter heading to read as follows:

## SUBCHAPTER A. GENERAL PROVISIONS

SECTION 3. Chapter 1003, Health and Safety Code, is amended by adding Subchapter B to read as follows:

## SUBCHAPTER B. PROVISION OF INVESTIGATIONAL STEM CELL TREATMENTS TO PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES

Sec. 1003.051. DEFINITIONS. In this subchapter:

- (1) "Investigational stem cell treatment" means an adult stem cell treatment that:
- (A) is under investigation in a clinical trial and being administered to human participants in that trial; and
- (B) has not yet been approved for general use by the United States Food and Drug Administration.
- (2) "Severe chronic disease" means a condition, injury, or illness that:
  - (A) may be treated;
  - (B) is never cured or eliminated; and
  - (C) entails significant functional impairment or severe pain.
- (3) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis that, without life-sustaining procedures, will soon result in death or a state

of permanent unconsciousness from which recovery is unlikely.

Sec. 1003.052. RULES. The executive commissioner shall adopt rules designating the medical conditions that constitute a severe chronic disease or terminal illness for purposes of this subchapter.

Sec. 1003.053. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational stem cell treatment under this subchapter if:

- (1) the patient has a severe chronic disease or terminal illness listed in the rules adopted under Section 1003.052 and attested to by the patient's treating physician; and
  - (2) the patient's physician:
  - (A) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration and determined that those treatment options are unavailable or unlikely to alleviate the significant impairment or severe pain associated with the severe chronic disease or terminal illness; and
  - (B) has recommended or prescribed in writing that the patient use a specific class of investigational stem cell treatment.

Sec. 1003.054. INFORMED CONSENT. (a) Before receiving an investigational stem cell treatment, an eligible patient must sign a written informed consent.

- (b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.
- (c) The executive commissioner by rule may adopt a form for the informed consent under this section.

Sec. 1003.055. TREATMENT REQUIREMENTS; TEXAS MEDICAL BOARD RULES. (a) Treatment provided under this subchapter must be:

- (1) administered directly by a physician certified under Subsection (c);
- (2) overseen by an institutional review board described by Subsection (d); and
- (3) provided at:
  - (A) a hospital licensed under Chapter 241;
  - (B) an ambulatory surgical center licensed under Chapter 243; or
  - (C) a medical school, as defined by Section 61.501, Education Code.
- (b) A physician administering an investigational stem cell treatment under this subchapter shall comply with all applicable Texas Medical Board rules.
- (c) An institutional review board described by Subsection (d) may certify a physician to provide an investigational stem cell treatment under this subchapter.
- (d) An institutional review board that oversees investigational stem cell treatments administered under this subchapter must be affiliated with:
  - (1) a medical school, as defined by Section 61.501, Education Code; or
  - (2) a hospital licensed under Chapter 241 that has at least 150 beds.
- (e) The Texas Medical Board may adopt rules regarding institutional review boards as necessary to implement this section.

Sec. 1003.056. EFFECT ON OTHER LAW. (a) This subchapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

(b) This subchapter does not affect or authorize a person to violate any law regulating the possession, use, or transfer of fetal tissue, fetal stem cells, adult stem cells, or human organs, including Sections 48.02 and 48.03, Penal Code.

Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164, Occupations Code, based solely on the physician's recommendations to an eligible

patient regarding access to or use of an investigational stem cell treatment, provided that the care provided or recommendations made to the patient meet the standard of care and the requirements of this subchapter.

- Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED. (a) In this section, "governmental entity" means this state or an agency or political subdivision of this state.
- (b) A governmental entity or an officer, employee, or agent of a governmental entity may not interfere with an eligible patient's access to or use of a stem cell treatment authorized under this subchapter.
- Sec. 1003.059. INSTITUTIONAL REVIEW BOARD DOCUMENTATION; REPORT. (a) An institutional review board overseeing an investigational stem cell treatment under this subchapter shall keep a record on each person to whom a physician administers the treatment and document in the record the provision of each treatment and the effects of the treatment on the person throughout the period the treatment is administered to the person.
- (b) Each institutional review board overseeing an investigational stem cell treatment under this subchapter shall submit an annual report to the Texas Medical Board on the review board's findings based on records kept under Subsection (a). The report may not include any patient identifying information and must be made available to the public in both written and electronic form.
- SECTION 4. Chapter 48, Penal Code, is amended by adding Section 48.03 to read as follows:
- Sec. 48.03. PROHIBITION ON PURCHASE AND SALE OF ADULT STEM CELLS FOR CERTAIN INVESTIGATIONAL TREATMENTS. (a) In this section:
  - (1) "Adult stem cell" means an undifferentiated cell that is:
    - (A) found in differentiated tissue; and
  - (B) able to renew itself and differentiate to yield all or nearly all of the specialized cell types of the tissue from which the cell originated.
  - (2) "Investigational stem cell treatment" means an adult stem cell treatment that:
  - (A) is under investigation in a clinical trial and being administered to human participants in that trial; and
  - (B) has not yet been approved for general use by the United States Food and Drug Administration.
- (b) A person commits an offense if the person knowingly offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers any adult stem cells for valuable consideration for use in an investigational stem cell treatment.
- (c) It is an exception to the application of this section that the valuable consideration is:
  - (1) a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services;
  - (2) reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the investigational stem cell treatment; or
  - (3) reimbursement of expenses of travel, housing, and lost wages incurred by the donor of adult stem cells in connection with the donation of the adult stem cells.
- (d) It is an exception to the application of this section that the actor engaged in conduct authorized under Chapter 162, Health and Safety Code.
  - (e) A violation of this section is a Class A misdemeanor.
- SECTION 5. As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission shall adopt rules necessary to implement Subchapter B, Chapter 1003, Health and Safety Code, as added by this Act.

SECTION 6. This Act takes effect September 1, 2017.

Passed by the House on May 12, 2017: Yeas 141, Nays 0, 1 present, not voting; that the House refused to concur in Senate amendments to H.B. No. 810 on May 26, 2017, and requested the appointment of a conference committee to consider the differences between the two houses; the House adopted the conference committee report on H.B. No. 810 on May 28, 2017: Yeas 145, Nays 0, 1 present, not voting; passed by the Senate, with amendments, on May 24, 2017: Yeas 31, Nays 0; at the request of the House, the Senate appointed a conference committee to consider the differences between the two houses; the Senate adopted the conference committee report on H.B. No. 810 on May 28, 2017: Yeas 30, Nays 0.

Approved June 12, 2017.

Effective September 1, 2017.

## PROVISION OF SERVICES AS AN ALTERNATIVE TO ADJUDICATION FOR CERTAIN CHILDREN WHO ENGAGE IN CONDUCT IN NEED OF SUPERVISION OR DELINQUENT CONDUCT AND TO A STUDY ON CERTAIN JUVENILE JUSTICE ISSUES

### **CHAPTER 698**

H.B. No. 1204

#### AN ACT

relating to the provision of services as an alternative to adjudication for certain children who engage in conduct in need of supervision or delinquent conduct and to a study on certain juvenile justice issues.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. Section 53.01, Family Code, is amended by adding Subsection (b-1) to read as follows:

- (b-1) The person who is conducting the preliminary investigation shall, as appropriate, refer the child's case to a community resource coordination group, a local-level interagency staffing group, or other community juvenile service provider for services under Section 53.011, if the person determines that:
  - (1) the child is younger than 12 years of age;
  - (2) there is probable cause to believe the child engaged in delinquent conduct or conduct indicating a need for supervision;
  - (3) the child's case does not require referral to the prosecuting attorney under Subsection (d) or (f);
    - (4) the child is eligible for deferred prosecution under Section 53.03; and
  - (5) the child and the child's family are not currently receiving services under Section 53.011 and would benefit from receiving the services.

SECTION 2. Chapter 53, Family Code, is amended by adding Section 53.011 to read as follows:

Sec. 53.011. SERVICES PROVIDED TO CERTAIN CHILDREN AND FAMILIES. (a) In this section:

- (1) "Community resource coordination group" has the meaning assigned by Section 531.421, Government Code.
- (2) "Local-level interagency staffing group" means a group established under the memorandum of understanding described by Section 531.055, Government Code.
- (b) On receipt of a referral under Section 53.01(b-1), a community resource coordina-